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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,452	06/22/2000	Fredric R. Bloom	0942.4970001/RWE/BJD	7893

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EXAMINER	
DAVIS, KATHARINE F	

ART UNIT	PAPER NUMBER
1636	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/599,452	Applicant(s) BLOOM ET AL.	
	Examiner Katharine F. Davis	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

This Office Action is in response to the Amendment filed on November 21, 2001. Claims 1-41 have been cancelled. New claims 42-102 have been added. Claims 42-102 are pending in the instant application.

The objection to the declaration has been withdrawn in view of the new corrected declaration filed on November 21, 2001. The objections to claims 5 and 8, the rejection of claim 1 under 35 U.S.C. 101, the rejection of claims 1, 2, 6, 7, 11, 14-16, 20, 22, 23 and 27-39 under 35 U.S.C. 112, first paragraph, and the rejection of claim 1 under 35 U.S.C. 102(b) (Khosla *et al.*) have all been withdrawn in view of the cancellation of the claims and the remarks presented by the Applicants in the November 21, 2001 Amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "rapid growing" in claims 42-102 is a relative term which renders the claims indefinite. The term "rapid growing" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The instant specification defines a rapid

growing microorganism as having an increased growth rate, a growth rate that is 5%-200% increased as compared to a reference microorganism. There is no definitive reference microorganism nor is there defined culture conditions for ascertaining increased growth of a microorganism. Thus, any microorganism can be considered rapid growing.

Applicants' arguments presented on pages 15 and 16 of the Amendment filed November 21, 2001 have been carefully considered but have not been found to be persuasive. Applicants contend that the term "rapid growing" is clearly defined in the specification as a microorganism that grows more rapidly than strains typically used in molecular biology applications and that such rapid growing microorganisms are identified on the basis of their growth rate as compared to a reference microorganism. How does one determine what strains are "typically used" in molecular biology applications? The strain selected would depend on the goal of the application and can thus be any strain. How is a reference microorganism defined? The specification lists *E. coli* MM294, DH5α and DH10B as preferred examples of reference microorganisms, however a list of preferred examples do not constitute a definition for the term "reference microorganism". Thus, any microorganism can still be considered to be rapidly growing based upon what reference strain is selected for comparison.

For both the reasons above and the reasons made of record in the previous Office Action mailed August 13, 2001, the rejection of claims 42-102 (originally presented as claims 1-41) under 35 U.S.C. 112, second paragraph, is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 42 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Bharathi *et al.* (FEMS Microbiology Letters 84:37-40 1991, IDS Reference AS1). Bharathi *et al.* disclose a strain of *Escherichia coli* 393 (see Table 2, page 39) that lacks endogenous plasmids and a method of making said strain. The 393 strain of *Escherichia coli* was treated with the curing agent Hexamine ruthenium (III) chloride (HRC). The instant claims 42 and 64 do not require that the rapid growing microorganism be naturally lacking endogenous plasmids. Claims 42 and 64 read on the 393 strain of *Escherichia coli* and the method of making said strain disclosed by Bharathi *et al.*

Applicant's arguments presented on pages 17 and 18 of the Amendment filed on November 21, 2001 have been carefully considered but have not been found to be persuasive. Applicants contend that the strains disclosed by Bharathi *et al.* are not rapid growing. However since the term "rapid growing" is held to be indefinite, claims 42 and 64 still read on the strains and methods disclosed by Bharathi *et al.*

Claims 48 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,966,841 (Riley). Riley discloses a method of cloning enhancer fragments comprising the steps of constructing a population of recombinant cloning vectors, transforming an *Escherichia coli* host strain with the recombinant cloning vectors and selecting the transformed *Escherichia coli* cells containing the recombinant vector (see columns 4-6, Isolation and Cloning of Growth Enhancing Fragments and also Examples 1 and 2). The *E. coli* cells of Riley take up the recombinant plasmid so therefore are competent cells for the uptake of exogenous DNA (see Table 1, column 8). The recombinant vectors (plasmids) of Riley are then isolated from the transformed *E. coli* cells (see columns 6-7, Assays of Plasmid Recovery). The *E.coli* host strain selected by Riley is considered to be capable of rapid growth (see column 6, lines 12-18). Thus, claims 48 and 69 read on the methods and host strains of Riley.

Applicant's arguments presented on pages 18-20 of the Amendment filed on November 21, 2001 have been carefully considered but have not been found to be persuasive. Applicants contend that the strains disclosed by Riley are not rapid growing. However since the term "rapid growing" is held to be indefinite, claims 48 and 69 still read on the host strains and methods disclosed by Riley.

Claim 58 is rejected under 35 U.S.C. 102(b) as being anticipated by Bhandari *et al.* (Journal of Bacteriology 179:4403-4406 1997, IDS Reference AR1). Bhandari *et al.* disclose a method of producing proteins (rat protein tyrosine phosphatase, *E.coli* DNA polymerase I and *E.*

coli SSB protein, see figure 2, page 4404) by transformation of *Escherichia coli* host cells (strain GJ1158) with recombinant vectors encoding a gene(s) for the protein. *E. coli* is considered to be a microorganism capable of rapid growth. Thus, claim 58 reads on the methods and host strains of Bhandari *et al.*

Applicant's arguments presented on pages 20 and 21 of the Amendment filed on November 21, 2001 have been carefully considered but have not been found to be persuasive. Applicants contend that the strains disclosed by Bhandari *et al.* are not rapid growing. However since the term "rapid growing" is held to be indefinite, claim 58 still reads on the host strains and methods disclosed by Bhandari *et al.*

Claims 85-87 and 91 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,981,797 (Jessee *et al.*). Jessee *et al.* disclose a composition comprising rapid growing microorganisms (*Escherichia coli*, see column 5, lines 10-19). The composition of Jessee *et al.* can include a transformation buffer comprising glycerol and buffering salts (see column 4, lines 44-47). Jessee *et al.* also disclose a method of making *E. coli* cells competent (see abstract and through out entire patent). Thus, claims 85-87 and 91 read on the composition and methods of Jessee *et al.*

Applicant's arguments presented on page 21 of the Amendment filed on November 21, 2001 have been carefully considered but have not been found to be persuasive. Applicants contend that the strains disclosed by Jessee *et al.* are not rapid growing. However since the term

"rapid growing" is held to be indefinite, claims 85-87 and 91 still read on the composition and methods disclosed by Jessee *et al.*

For both the reasons above and the reasons made of record in the previous Office Action mailed August 13, 2001, all of the above rejections under 35 U.S.C. 102(b) are maintained.

Conclusion

Claims 42-102 are rejected. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195 with direct desktop RightFax (703) 746-5199. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are

(703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or concerning the formalities of this application should be directed to Patent Analyst Dianiece Jacobs whose telephone number is (703) 305-3388.

Katharine F. Davis
January 14, 2002

DAVID GUZO
PRIMARY EXAMINER